

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	ROZIER <i>et al.</i>)	ATTORNEY DOCKET:	04308057
SERIAL NO.:	10/501,604)	GROUP ART UNIT:	3772
FILING DATE:	October 28, 2004)	EXAMINER:	JACKSON, Brandon Lee
TITLE:	SITE GUARD FOR INTRAVENOUS SITES AND OTHER SENSITIVE AREAS			
DATE:	September 15, 2009)	CUSTOMER NO.:	26565

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL DECLARATION OF LISA M. VALLINO UNDER 37 C.F.R. § 1.131

I, Lisa M. Vallino, declare and state as follows:

1. I am one of the inventors of the subject matter provided in the above-captioned patent application, and one of the co-founders of I.V. House, Inc., which is the assignee of the above-captioned application. I have personal knowledge of the facts stated herein.

2. The above-captioned patent application discloses and claims, among other things, a site guard for intravenous sites and other sensitive areas that fastens to a patient without having to place adhesive tape on the skin of the patient.

3. I have reviewed the Shesol patent, U.S. Patent No. 6,257,240 having a filing date of June 5, 2000.

4. I submit this Declaration to supplement the information I provided to the Patent Office in my November 12, 2008 declaration.

5. In 1991, I conceived of a site guard having the shape of a U-Shaped domed cup to protect intravenous sites and other sensitive areas ("I.V. House Site Guard"). This product is covered by the claims of U.S. Patent No. 5,167,240 (the '240 Patent).

6. On January 28, 1991, Betty Rozier ("Ms. Rozier"), my mother and co-founder of I.V. House, Inc. and I filed a design patent application titled "SHIELD FOR I.V. SITES" for one embodiment of an I.V. House Site Guard. This design application issued as U.S. Patent No. D335,926 (the '926 Patent). The figures of the '926 Patent disclose a site guard comprising a hollow member having a U-shaped base, the base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover. The site guard of the '926 Patent also discloses a flange attached to the lower edge of the hollow member. See U.S. Pat. No. D335,926 at Figs. 1-6. A copy of the '926 Patent is attached hereto as Exhibit A.

7. As early as 1993, Ms. Rozier and I exhibited the I.V. House Site Guard product at various conferences, during which time we received interest in our product from nurses who work exclusively with geriatric patients. We became concerned that the use of an I.V. House Site Guard that is secured with adhesive tape would not be beneficial to geriatric patients due to the harm that the adhesive tape can cause to their fragile skin. Because of such interest from the nurses, and the problem we had identified, we determined we needed to develop a similar site guard that could be secured to a patient without the use of any adhesive tape.

8. Between 1993 and 1999, Ms. Rozier and I conceived of new variations for the I.V. House Site Guard, including a site guard that could be secured to a patient without the use of any adhesives on a patient's skin. One embodiment utilized the site guard disclosed in the '926

Patent and included a fabric connector affixed to the flange thereof such that it does not traverse the sidewall of the site guard.

9. During this same time period, we at all times continuously and diligently worked to achieve actual reduction to practice of our inventive concept for an adhesive-free site guard by, among other efforts, experimenting with various designs, techniques, concept prototypes, and materials so as to achieve an actual working product having all the properties required of our inventive concept.

10. At least as of January 8, 2000, following several years of continuous and diligent efforts to achieve actual reduction to practice of our invention concept, we created several hand-drawn sheets of drawings detailing the various design embodiments of our invention concept. Each of the dated, hand-drawn, drawings is attached hereto as Exhibit B. While the drawings are somewhat basic in nature, the drawings of Exhibit B were intended to depict various embodiments of a fabric connector affixed to a site guard hollow member. The hollow member depicted in each of the drawings of Exhibit B was intended to represent either the hollow member as disclosed in the '240 Patent or the hollow member as disclosed in the '926 Patent. Thus, the fabric connectors depicted in the drawings of Exhibit B are affixed at either a lower edge or flange of the site guard's hollow member, such that it does not traverse the sidewall. *See, e.g.*, Figs. 7 and 8 of Exhibit B. Accordingly, at the very latest, we achieved reduction to practice of our inventive concept on January 8, 2000, if not significantly earlier.

11. In addition, we created physical prototypes of several of the inventive embodiments that were depicted in the drawings dated January 8, 2000 as well as prototypes of embodiments that were not included in the drawings of January 8, 2000. Ms. Rozier and I

created these prototypes for the purposes of physical experimentation, proof of concept, and actual reduction to practice.

12. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Lisa Vallino



Date

EXHIBIT A



US00D335926S

United States Patent [19]

Rozier et al.

[11] **Patent Number: Des. 335,926**[45] **Date of Patent: ** May 25, 1993**[54] **SHIELD FOR I.V. SITES**

[76] Inventors: **Betty M. Rozier**, 7400 Foxmont,
Hazelwood, Mo. 63042; **Lisa M.**
Vallino, 6550 Dale, St. Louis, Mo.
63139

[**] Term: **14 Years**[21] Appl. No.: **648,617**[22] Filed: **Jan. 28, 1991**[52] U.S. Cl. **D24/130**

[58] Field of Search **D24/127, 130; 128/846,**
128/877, 878, 879, DIG. 6, DIG. 26; 604/174,
180, 192, 197, 198

[56] **References Cited****U.S. PATENT DOCUMENTS**

D. 327,321 6/1992 Russell et al. **D24/130**
3,194,235 7/1965 Cooke **604/180 X**
3,900,026 8/1975 Wagner **128/DIG. 26 X**
4,517,971 5/1985 Sorbonne **604/174 X**
4,633,863 1/1987 Filips et al. **604/180 X**

4,679,553 7/1987 Proulx et al. **604/174 X**4,898,587 2/1990 Mera **604/174**5,074,847 12/1991 Greenwell et al. **604/174***Primary Examiner—Stella Reid**Assistant Examiner—Ian Simmons**Attorney, Agent, or Firm—Grace J. Fishel*[57] **CLAIM**

The ornamental design for a shield for I.V. sites, as
shown.

DESCRIPTION

FIG. 1 is a perspective view of a shield for I.V. site
showing my new design, the broken line showing of the
hand, arm board and I.V. tubing is for illustrative pur-
poses only and forms no part of the claimed design;

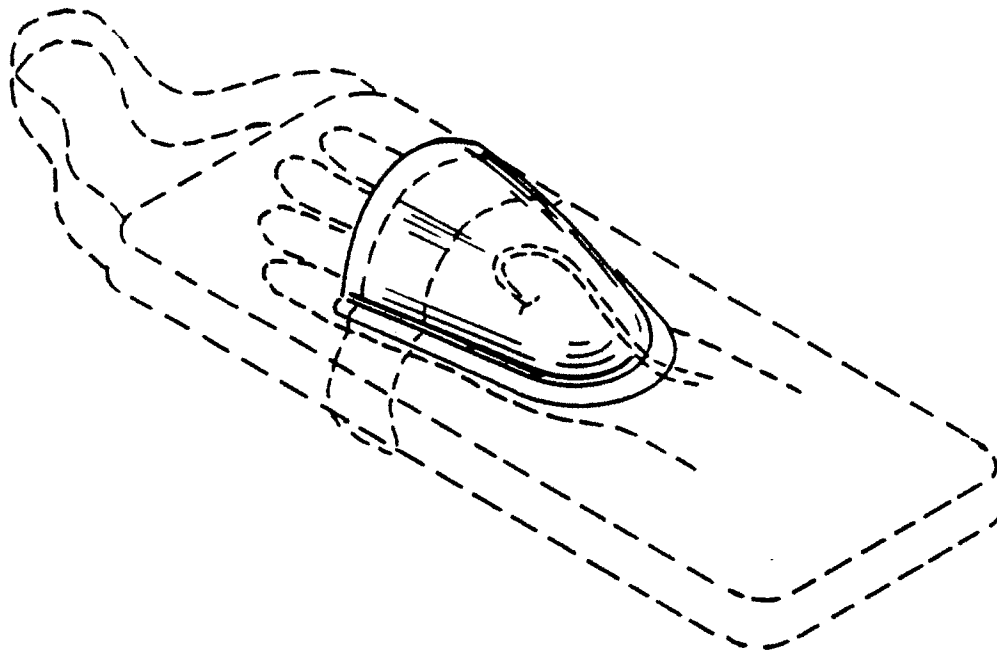
FIG. 2 is a top plan view thereof;

FIG. 3 is a bottom plan view thereof;

FIG. 4 is a side elevational view thereof, the opposite
side elevational being identical thereto;

FIG. 5 is a front elevational view thereof; and,

FIG. 6 is a rear elevational view thereof.



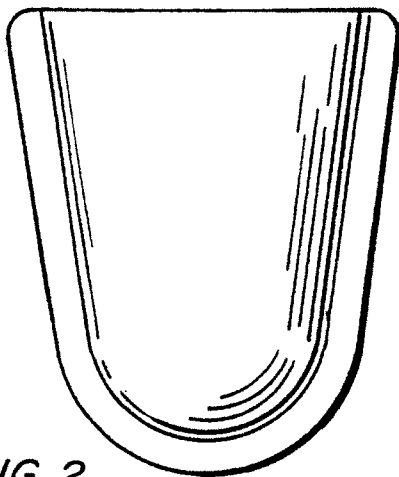
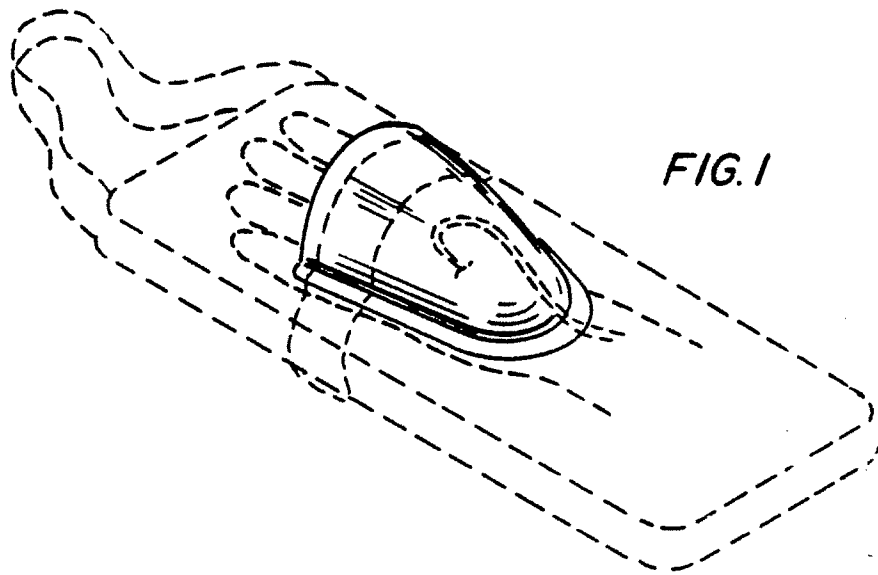


FIG. 2

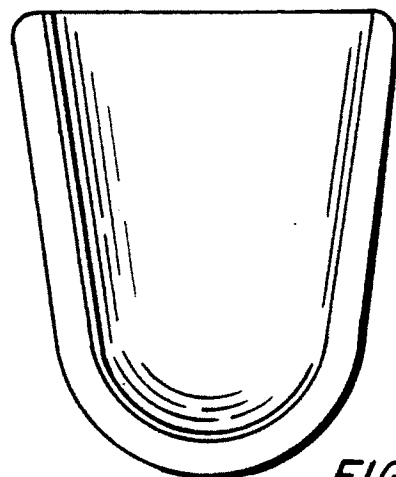


FIG. 3



FIG. 4

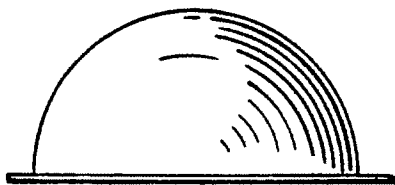


FIG. 5



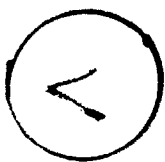
FIG. 6

EXHIBIT B

1-8-2000

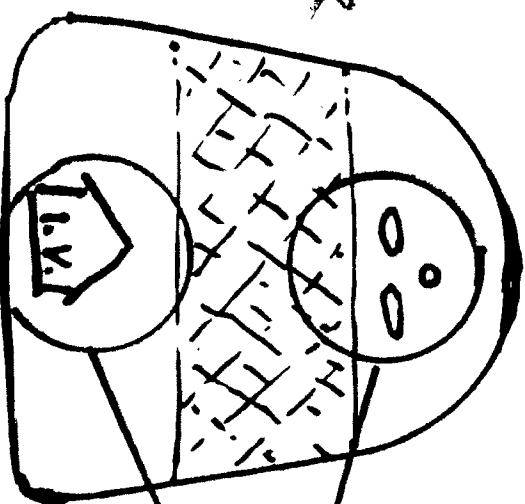
FIG 1

DRAWINGS NOT TO SCALE
LARGE SIZE I.V. HOUSE 726L USED



INDICATES
VELCRO
HOOK
FASTENER

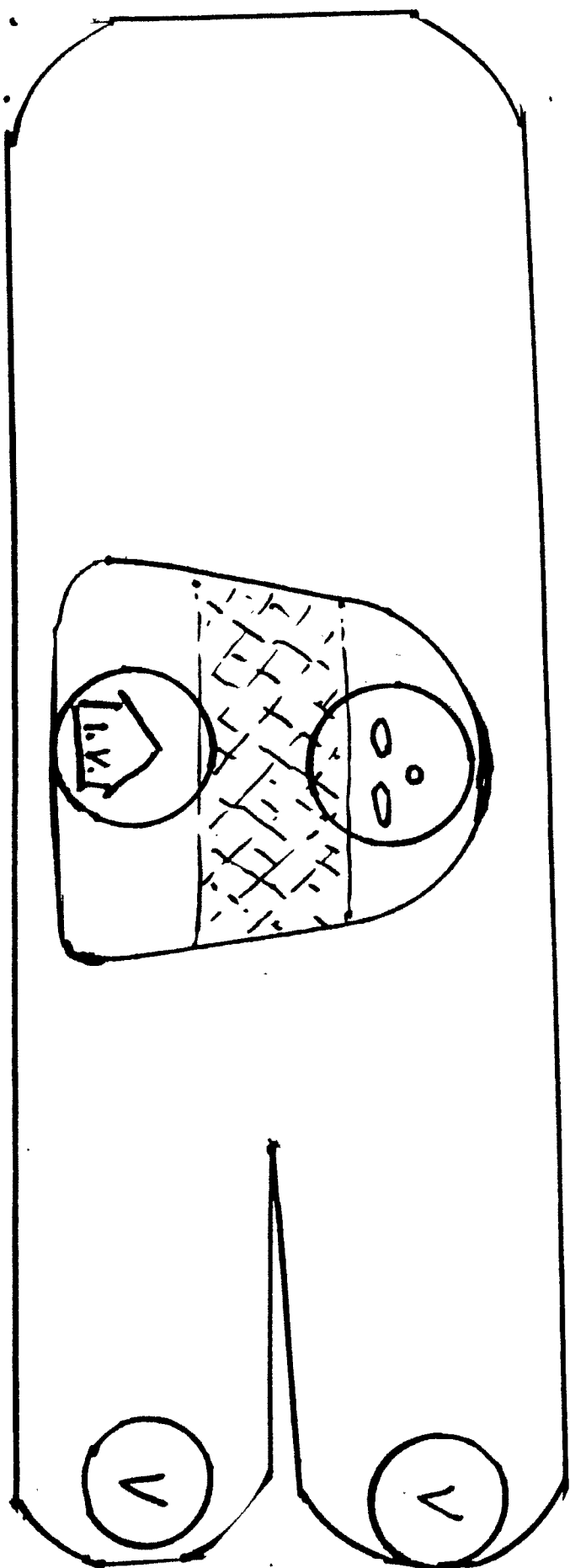
SHADED AREAS
INDICATE TAPELESS
DRESSING



INDICATE 2
CIRCULAR
HOLES INTENDED
FOR VENTILATION
AND I.V. HOUSE
AND BE VISIBLE
WHEN TAPELESS
DRESSING COVERS
AN I.V. HOUSE.

1-8-00003

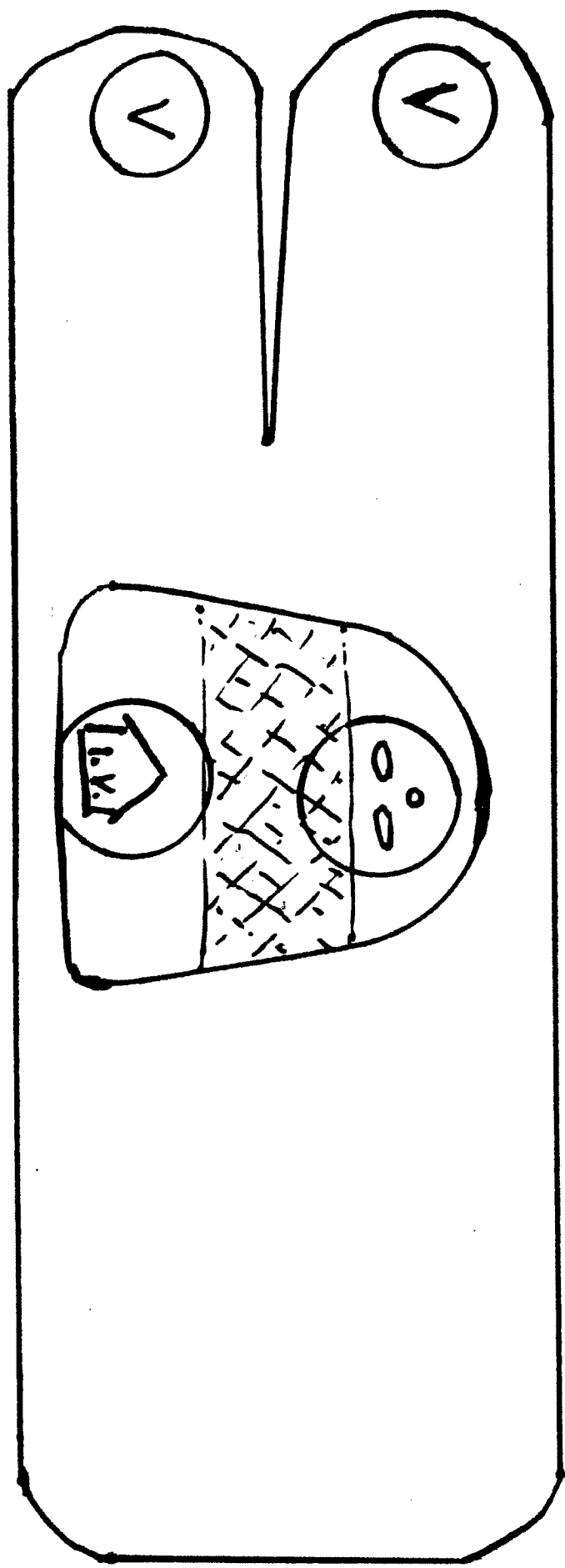
FIG. 2



RIGHT HAND

1-8. 2000

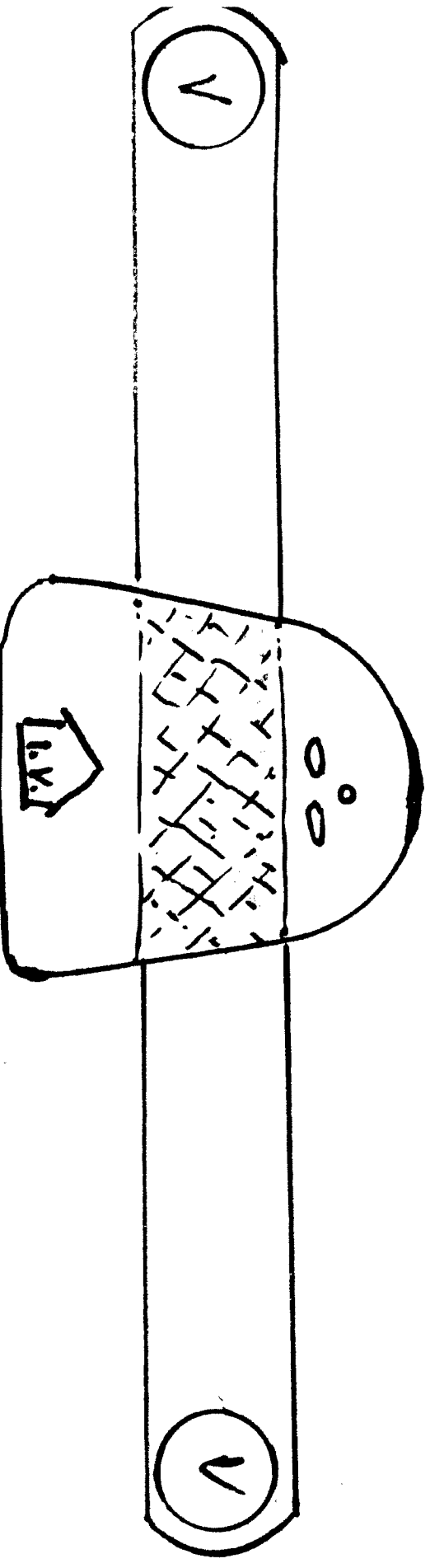
F. A. 3



LEFT HAND

1-X-2000

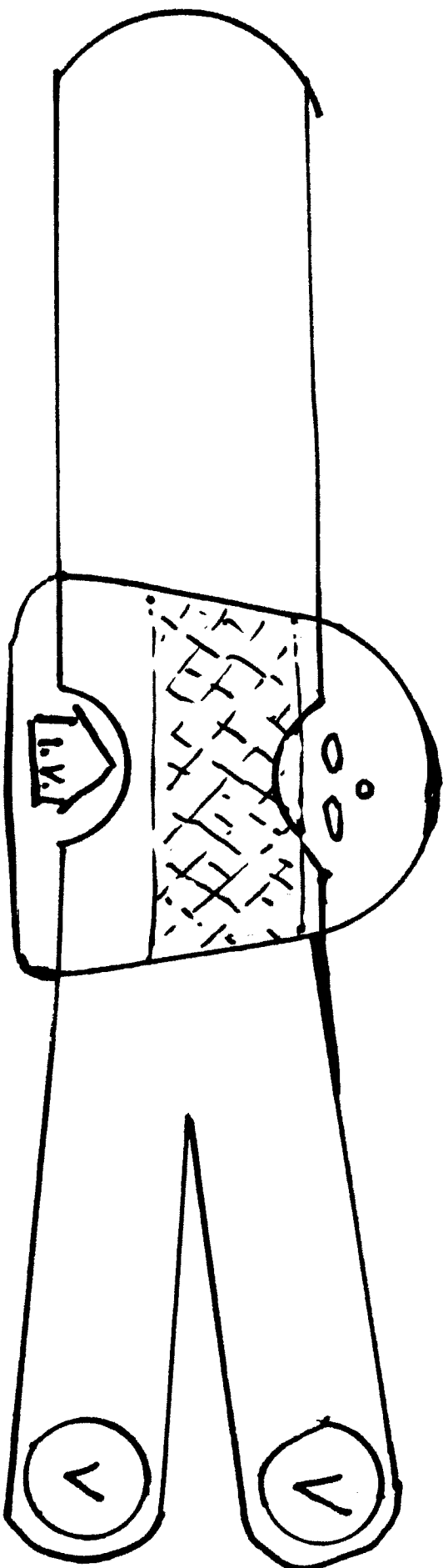
F.T.U



AMBIDEXTROUS HAND OR ARM
UNUSED FASTENER SIMPLY FOLDS UNDER

1-8 2000

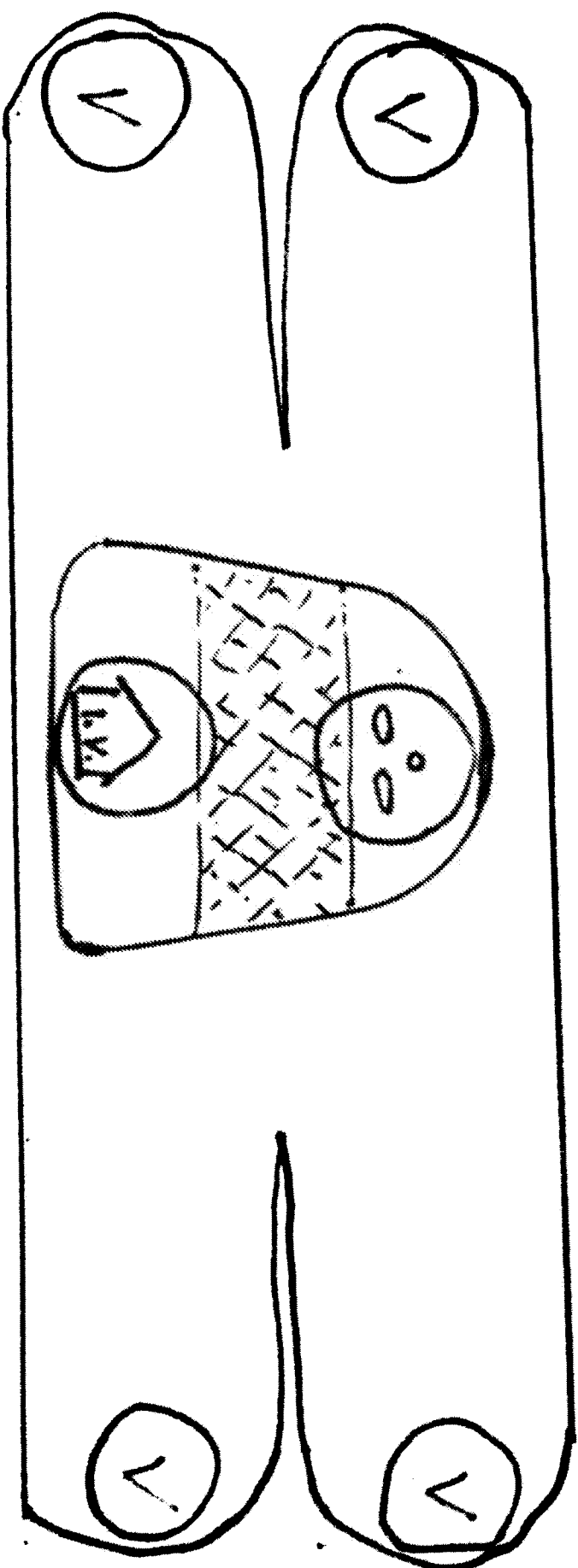
1.5.5



LEFT HAND
REVERSE ENDS FOR RIGHT HAND

1-8-2000

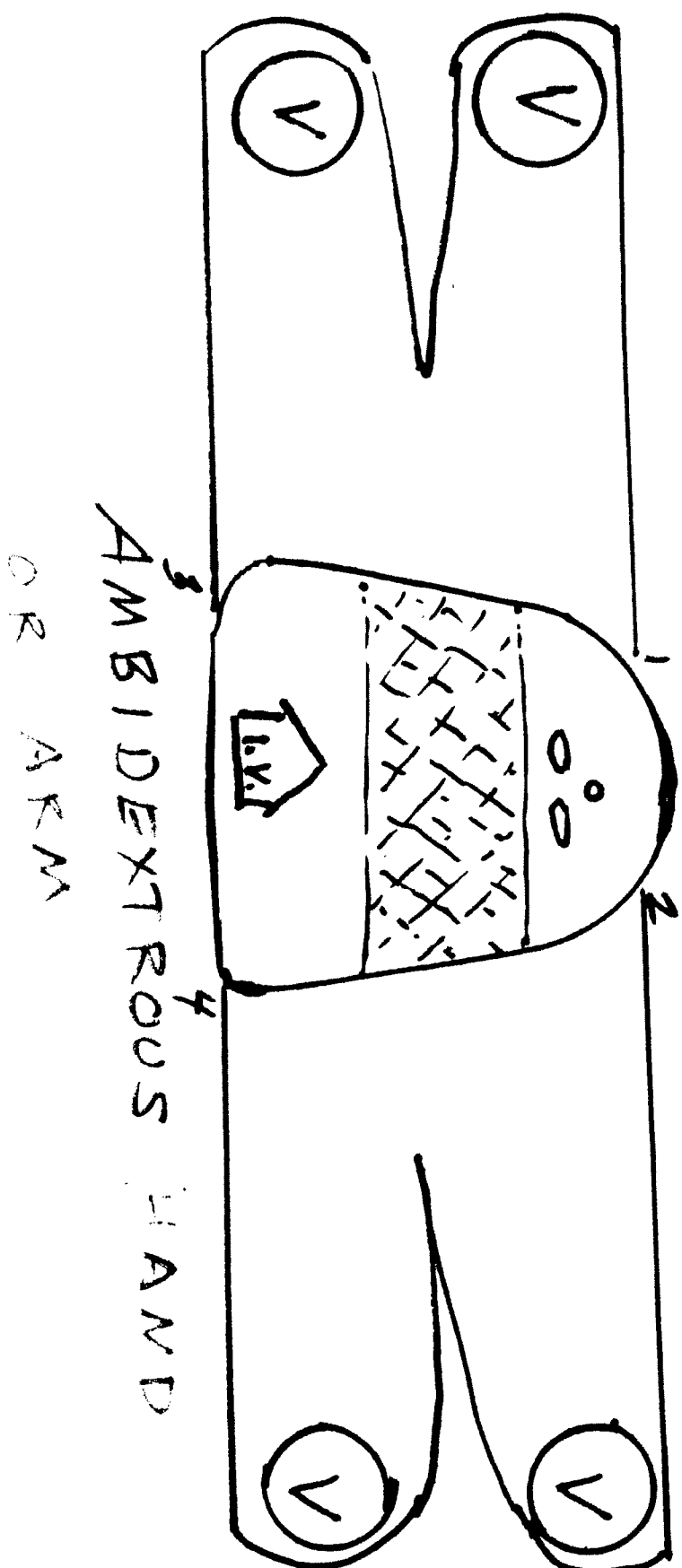
G. G.



AMBI DEXTROUS HAND OR ARM
2 CIRCULAR OPENINGS EXPOSE
VENTILATION AND LOGO

1-8-2000

FIG. 7

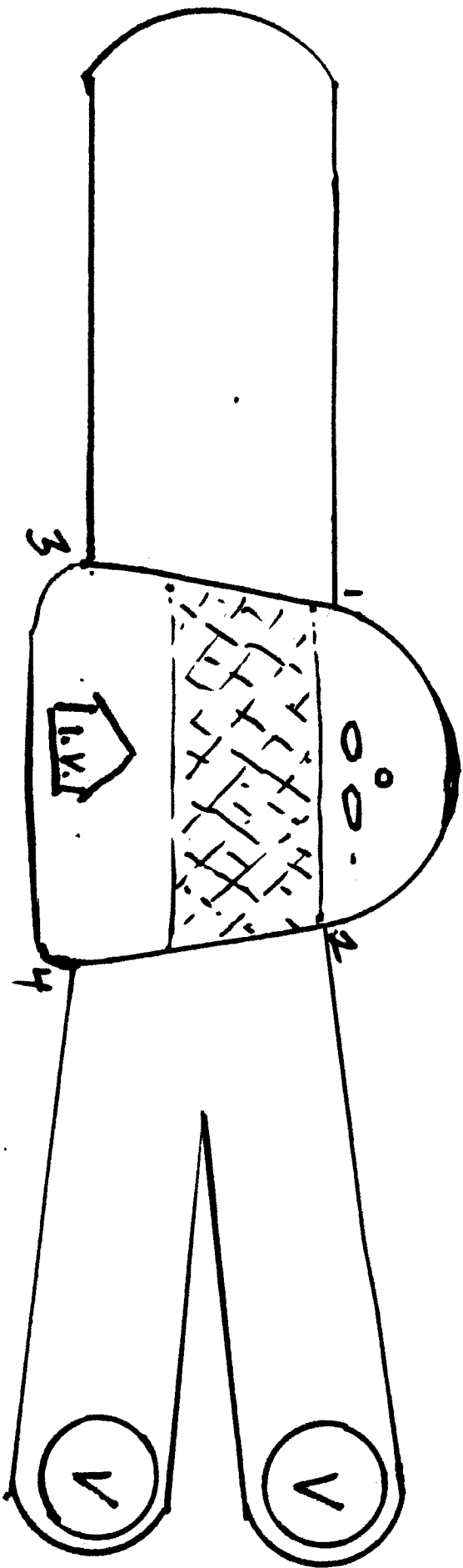


AMBIDEXTROUS HAND
OR ARM

TAPELLESS
WELOED TA
EDGES @
1, 2, 3, 4 OR ALL ALONG BOTH EDGES
I.V. HOUSE FULLY EXPOSED

1-8-2000

Fig. 8



LEFT HAND

TAPLESS
WELDED TO
EDGES @
1, 2, 3, 4 OR ALL ALONG BOTH EDGES
I.V. HOUSE FULLY EXPOSED